No. 77-956

# In the Supreme Court of the United States

OCTOBER TERM, 1977

PARKE, DAVIS & COMPANY, PETITIONER

*v.*

JOSEPH A. CALIFANO, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, ET AL.

*ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT*

## BRIEF FOR THE RESPONDENTS IN OPPOSITION

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### OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a–13a) is reported at 564 F. 2d 1200. The memorandum opinion of the district court (Pet. App. 14a–24a) is not reported.

### JURISDICTION

The judgment of the court of appeals (Pet. App. 25a) was entered on October 26, 1977, and a timely petition for rehearing was denied by that court on November 23, 1977 (Pet. App. 26a). The petition for a writ of certiorari was filed on January 4, 1978. The

jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

## QUESTION PRESENTED

Whether the district court had jurisdiction to enjoin the Food and Drug Administration from initiating seizure actions against a misbranded and unapproved new drug marketed by petitioner.

## STATEMENT

Petitioner, a drug manufacturer, obtained the approval of the Food and Drug Administration (FDA) in 1948 to market the drug Benylin, whose main active ingredient is diphenhydramine hydrochloride ("DPH"). FDA approval, in the form of an approved new drug application ("NDA"),[1] restricted sale of the drug to a prescription-only basis, first for use as a decongestant and later as a cough suppressant (Pet. App. 15a).

In February 1973, FDA proposed to withdraw approval of Benylin for use as a cough suppressant, because of scientific reports questioning DPH's effectiveness as cough medicine. 38 Fed. Reg. 4006, 4007. The agency, however, decided to defer action on Benylin and other prescription cough and cold remedies pending the report of an advisory review panel

[1] "New drug" is a term of art defined in Section 201(p) of the Federal Food, Drug and Cosmetic Act (Act), 52 Stat. 1040, as amended, 21 U.S.C. 321(p) (Pet. App. 28a). A "new drug" may not be introduced into commerce until FDA has approved a new drug application, which demonstrates by scientific methods substantial evidence of the drug's safety and effectiveness. Section 505, 21 U.S.C. 355 (Pet. App. 30a–38a). See generally *Weinberger* v. *Hynson, Westcott & Dunning*, 412 U.S. 609.



evaluating similar over-the-counter (OTC) drugs.[2] 38 Fed. Reg. 34481.

Petitioner submitted data to the panel in support of DPH's safety and effectiveness as a cough suppressant and the propriety of its over-the-counter sale. In addition, it submitted a supplemental new drug application to FDA seeking approval of Benylin as an effective cough-suppressant and removal of the prescription limitation on marketing (Pet. App. 16a). FDA deferred action on these applications pending completion of the OTC panel's review.

On September 11, 1974, the advisory panel tentatively decided that DPH is safe and effective as a cough suppressant for OTC sale (Pet. App. 16a). In February 1975, petitioner informed FDA of its intent to market Benylin as an over-the-counter cough medicine. It recognized that the panel's decision was only tentative and that the final monograph, which constitutes the final regulation,[3] would not issue until 1977

[2] This panel was one of several expert groups which the Commissioner had appointed to advise him on drug safety and effectiveness. See 76 Stat. 781.

[3] FDA's procedures require several steps. After the panel submits its report, including a recommended monograph, to the Commissioner, the Commissioner studies the material. He then publishes a proposed monograph in the Federal Register, together with the panel's report and its recommended monograph (if different from that proposed by the Commissioner) and invites the submission of comments. Next, the Commissioner publishes in the Federal Register a tentative final monograph, with further opportunity for the public to make objections and request an oral hearing. Then he publishes a final monograph. See generally 21 C.F.R. 330.10(a).

(J.A. 20a).[4] Nonetheless, it sought FDA approval of its proposed marketing or, alternatively, a statement that the product would not be subject to regulatory action "at this time" (J.A. 21a). On March 16, 1975, an FDA attorney, Gary Yingling, replied that because of enforcement priorities it was highly unlikely that FDA would at that time institute legal action against Benylin if marketed over the counter (Pet. App. 4a). He expressly warned petitioner, however, that it "assumes the risk that the Agency may not adopt this panel's categorization of diphenhydramine hydrochloride as generally recognized as safe and effective or that the FDA may eventually require different labeling from that which is presently accepted by the panel" (Pet. App. 4a). Petitioner began to sell Benylin Cough Syrup as an over-the-counter drug in September 1975 (Pet. App. 17a).

The Commissioner soon became concerned over the fact that petitioner and other manufacturers were selling prescription drugs for OTC use based on tentative OTC Panel recommendations and informal expressions of FDA enforcement policy. Thus, on December 4, 1975, he published a statement of enforcement policy and proposed regulations that, effective immediately, FDA would take action against manufacturers of prescription drugs who began OTC distribution before publication of an advisory panel report in the Federal Register. Further, such OTC marketing before the effective date of the final

[4] "J.A." refers to the court of apepals joint appendix, a copy of which has been lodged with the Clerk of this Court.



monograph would subject the manufacturer to the risk of recall, relabeling or regulatory action should the Commissioner not accept the panel's recommendation. 40 Fed. Reg. 56675, 56676–56677. The Commissioner expressly revoked all inconsistent opinions given by agency personnel, and he expressly stated that DPH was subject to the stated enforcement policy. *Id.* at 56676.[5] On August 4, 1976, the Commissioner restated the enforcement policy—emphasizing that once he had announced tentative disagreement with a panel proposal he would take appropriate regulatory action immediately against those who prior to the publication of the final monograph sell prescription drugs for OTC use (see J.A. 27a)—and he made final the proposed regulations. 41 Fed. Reg. 32580.

Notwithstanding these announcements, and even though the Commissioner had not yet published any proposed monograph on the drug, petitioner continued to sell Benylin with an OTC label. On September 9, 1976, the Commissioner published a proposed regulation containing the advisory panel's recommended monograph. 41 Fed. Reg. 38312 (Pet. App. 57a–90a).[6]

[5] The regulations also provided that a drug previously approved only for prescription use could lawfully be sold for OTC use upon publication of a final monograph approving such use. *Id.* at 56677. Previously, the change from prescription to OTC status could be made only by filing a supplemental new drug application.

[6] Contrary to petitioner's statement (Pet. 5–6), publication of the advisory committee's proposed monograph did not constitute formal or informal approval of the OTC marketing of Benylin. Such publication is simply a requisite preliminary step in the establishment of a final monograph, which alone can constitute final

The Commissioner stated that he would defer decision on the panel's recommendation of DPH for OTC sale as cough medicine pending action on petitioner's supplemental new drug application for Benylin. 41 Fed. Reg. 38313. (Pet. App. 62a–63a).[7] He warned that should the agency deny that application, he would then issue a statement of disagreement with the panel recommendation, which, in accordance with his established enforcement policy, would subject Benylin to immediate enforcement action. 41 Fed. Reg. 38313 (Pet. App. 62a–63a).

On November 22, 1976, the Commissioner issued a notice stating his disagreement with the panel's recommendation for OTC distribution of DPH as a cough suppressant (J.A. 50a).[8] The FDA, in accord with its enforcement policy, on November 24, 1976, sent a telegram to petitioner requesting a recall of

approval of a drug for marketing under the conditions specified in the final monograph. 21 C.F.R. 330.10(a) (5), (6) and (9). Indeed, the Commissioner published warnings that OTC marketing before the effective date of the final monograph would subject the manufacturer to the risk of regulatory action. 40 Fed. Reg. 56675, 56676–56677; 41 Fed. Reg. 32580, 38312.

[7] On September 8, 1976, FDA's Bureau of Drugs had preliminarily ruled that petitioner's supplemental new drug application was not approvable because of a failure to provide adequate clinical trials as well as the drug's marked tendency to induce drowsiness (J.A. 30a–31a). Petitioner took an administrative appeal (J.A. 33a–34a).

[8] On the same day the agency confirmed its intent to deny the application and offered petitioner a hearing before an administrative law judge (J.A. 36a–48a). Petitioner did request a hearing, which is now complete, except for the submission of a decision by the administrative law judge. We expect the agency to complete all its proceedings in this matter by April 1978.



existing stocks of Benylin Cough Syrup which were labelled for OTC sale (Pet. App. 101a–103a). When it became apparent that petitioner did not intend to respond to this request, FDA on November 26, 1976, prepared to recommend to appropriate United States Attorneys that seizure actions be filed against Benylin stored at petitioner's warehouses throughout the country. United States Attorneys in Illinois, Minnesota and Texas filed complaints and accomplished seizures of the drug on November 30, 1976, and December 1, 1976 (Pet. App. 7a).[9]

Petitioner in the meantime had filed a complaint in the District Court for the Eastern District of Michigan on November 29, 1976, seeking a declaratory judgment that Benylin Cough Syrup was neither a new drug nor a drug limited to prescription sale, and an injunction to restrain FDA's enforcement action against the drug (J.A. 4a–16a). The court on December 1, 1976, entered a temporary restraining order against the agency, and a week later issued the requested injunction.[10] The court stated that petitioner had begun to market Benylin for OTC sale in reliance on the "FDA assurances [in the Yingling letter] that doing so would provoke no FDA regulatory action unless and until the agency made a final decision that Benylin is unsuitable for OTC sale" (Pet. App. 22a).

[9] These seizures did not contravene government assurances to petitioner or anyone else. Compare Pet. 6.

[10] The court denied petitioner's request for declaratory relief because proceedings concerning Benylin's new drug and prescription drug status were pending before the agency and were not ripe for review (Pet. App. 20a–21a).

Although "FDA retracted these assurances three months after plaintiff began selling Benylin OTC," the retraction, in the court's view, "came too late to affect plaintiff's right to sell" (Pet. App. 22a). The court held that in these circumstances FDA enforcement was arbitrary, and should be enjoined. The court stated that *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594, was no obstacle to an injunction, because that case involved an agency determination of probable cause, which is not present in this case (Pet. App. 23a–24a). Accordingly, the court enjoined all enforcement proceedings until thirty days after FDA makes a final determination of Benylin's status (Pet. App. 24a).

The court of appeals reversed (Pet. App. 1a–13a). The court agreed with the district court that the only agency action at issue was FDA's decision to institute seizure actions (Pet. App. 8a). It specifically noted that Benylin has never received FDA approval for OTC sale and that proceedings concerning that issue are still pending (Pet. App. 12a). It disagreed with the district court, however, on the reviewability of such enforcement action. It held that the present case is controlled by *Ewing* v. *Mytinger & Casselberry, Inc., supra,* because the decision to begin enforcement proceedings "is indistinguishable from the finding of probable cause * * *" (Pet. App. 11a). Moreover, as in *Ewing,* petitioner may have the libel actions consolidated for a single trial and there may raise all the issues it sought to raise by way of its suit for an injunction (Pet. App. 11a–12a).



## ARGUMENT

The court of appeals' decision is a correct application of this Court's holding in *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594, and does not conflict with any decision of this Court or of any other court of appeals.

In *Ewing,* this Court held that district courts lack jurisdiction to enjoin the FDA from instituting or prosecuting suits to seize misbranded or dangerous drugs. The FDA's decision that probable cause exists to seize the drugs is insulated from review, this Court held, because that finding is merely a predicate for the Attorney General's institution of judicial action, and the manufacturer's opportunity to appear before the court and to have a full hearing on the merits of seizure "satisfies the requirements of due process" (339 U.S. at 598). The fact that the institution of legal action may itself have a serious effect on the manufacturer's business is immaterial; "it has never been held that the hand of government must be stayed until the courts have an opportunity to determine whether the government is justified in instituting suit in the courts" (*id* at 599). Furthermore, the Court stated, judicial review of the government's "preliminary step" of deciding to bring suit would be "so unique that we are not willing easily to infer that it exists" (*id.* at 600). To the contrary, "Congress weighed the potential injury to the public from misbranded articles against the injury to the purveyor of the article from a temporary interference with its distribution

and decided in favor of the speedy, preventive device of multiple seizures" (*id.* at 601).

*Ewing* controls here, as the court of appeals held. The Commissioner's decision to seize those stocks of Benylin being sold over the counter—a decision made only after petitioner refused to recall those stocks (Pet. App. 101a–103a)—was, as the court of appeals held, "indistinguishable from the finding of probable cause which [*Ewing*] has held may not be challenged in a separate action" (Pet. App. 11a). The district court's attempt to distinguish *Ewing* on the ground that the Commissioner here made "no final factual determination of probable cause" (Pet. App. 23a–24a) was erroneous. As the court of appeals implied in holding this case "indistinguishable" from *Ewing,* there inheres in every FDA decision to recommend judicial enforcement to the Attorney General a considered, if not formally stated, judgment that there is probable cause to act to protect the public health.

The court of appeals also correctly concluded that *Abbott Laboratories* v. *Gardner,* 387 U.S. 136, did not restrict or repudiate *Ewing. Abbott Laboratories* held that, unless Congress clearly prohibited it, judicial review of the Commissioner's regulation requiring certain language to be inserted on all drug labelling and advertising was subject to judicial review under the Administrative Procedure Act, 5 U.S.C. 702. But *Abbott Laboratories* reaffirmed *Ewing* as "quite clearly correct" (387 U.S. at 147), although inapplicable to "promulgation of a self-operative industry-wide regulation, such as we have here" (*ibid.*). In the present



case, of course, there is no self-operative regulation which, absent judicial review, would be binding throughout the industry; there is simply a decision to institute legal action against petitioner.

Petitioner attempts to avoid the result of *Ewing* by arguing that, in this case, it sought pre-enforcement review not merely of the decision to seize Benylin, but of the entire course of conduct by FDA which allegedly changed the marketing status of Benylin "back to" prescription-only sale. But not even the district court went so far as to grant relief on this question. Instead, it held that the question of Benylin's marketing status was currently under consideration by the FDA and was therefore not yet ripe for judicial resolution (Pet. App. 20a–21a). Accordingly, it dismissed petitioner's action for a declaratory judgment that Benylin could properly be sold over-the-counter (Pet. App. 21a).

Therefore, petitioner's assertion (Pet. 10) that the district court found the FDA's alleged "reclassification" of Benylin to be arbitrary and capricious is incorrect,[11] as the court of appeals held in rejecting

[11] Petitioner's apparent support for its statement is an "explanation" which the district court offered in support of its judgment (J.A. 138a–139a; Pet. 8 n. 14). The legal effect of this "explanation" is uncertain; it was not included in the district court's memorandum (Pet. App. 14a–24a). In any event, the "explanation" does not add anything to the memorandum, which held that "defendants' threatened immediate enforcement action against the OTC sale of Benylin is arbitrary and capricious" because the FDA "put [petitioner] to the expense and inconvenience of changing its marketing procedures again before a final agency determination on the merits" and induced petitioner to rely on "FDA assurances" (*i.e.*, the Yingling letter). "[I]n these circumstances," the district court concluded, "the threatened FDA en-

petitioner's submission to the same effect (Pet. App. 11a–12a).[12]

In short, the instant case is, as the court of appeals stated, indistinguishable from *Ewing* (Pet. App. 11a). As in *Ewing,* petitioner may raise any defense it has against FDA's enforcement action in the seizure proceedings themselves.

2. Petitioner's attempt to bring this case within *Weinberger* v. *Bentex Pharmaceuticals, Inc.,* 412 U.S. 645 (Pet. 13–15) is without merit. *Bentex* was an action by drug manufacturers for a declaratory judgment that their products were not "new drugs" within the meaning of the Act. This Court, agreeing with the district court, held that the FDA had jurisdiction to determine new-drug status in administrative proceedings and should exercise that jurisdiction prior to any judicial review. Although this Court noted in describing the procedural history of the case that the district court had "entered an injunction to preserve the status quo" (412 U.S. at 648), the propriety of

forcement action is arbitrary and capricious" (Pet. App. 22a). Thus the "explanation" is no more than a restatement that the FDA could not bring enforcement actions under the circumstances; it is not a finding that there was any reclassification of Benylin. See note 12, *infra.*

[12] In any event, the Commisioner did not "reclassify" Benylin "back to" a prescription drug; it had never been reclassified as an OTC Drug. Petitioner's only basis for selling Benylin OTC was the Yingling letter, which stated that the prospect of legal action "at this time" was slight. But that letter specifically stated that, if petitioner chose to market Benylin OTC, it "assumes the risk that the Agency may not adopt this panel's categorization of [DPH] as generally recognized as safe and effective * * *" (Pet. App. 4a).



such an injunction under *Ewing* was not raised before this Court or the court of appeals and was not decided by either of them. *Bentex* is therefore irrelevant to this case.

Finally, petitioner's brief contention (Pet. 15) that the decision below conflicts with that of the Tenth Circuit in *Rutherford* v. *United States,* 542 F. 2d 1137 (C.A. 10), is ill-founded. *Rutherford* was a suit by a cancer patient for an injunction on constitutional grounds to stop government interference with his obtaining a personal supply of the drug laetrile, without which he claimed he would die. The court of appeals allowed the district court injunction to stand while the FDA determined whether laetrile is a new drug (*id.* at 1143). In view of the plaintiff's inability to contest enforcement action, the case bears no resemblance to this one, where petitioner has an entirely adequate remedy in the consolidation and defense of the seizure actions.[13]

[13] Contrary to petitioner's suggestion (Pet. 13 n. 18), the court of appeals' decision here is in harmony with the First Circuit's decision in *Natick Paperboard Corp.* v. *Weinberger,* 498 F. 2d 125 (C.A. 1), which, on the basis of *Ewing,* held that the district court lacked jurisdiction to enjoin the FDA from instituting seizure actions under Section 304 of the Act, 21 U.S.C. 334. In rejecting attempts to distinguish *Ewing,* the *Natick* court held (498 F. 2d at 127): "[W]e think that the fundamental purpose of § 334 recognized in *Ewing*—speedy protection of the public from dangerous articles in interstate commerce—similarly requires that no seizure be halted pending judicial resolution of the definitional issue."

This holding is also fully consistent with the Seventh Circuit's decision in *Nor-Am Agricultural Products, Inc.* v. *Hardin,* 435 F. 2d 1151, reversing on rehearing 435 F. 2d 1133, certiorari denied, 402 U.S. 935. There the court applied the *Ewing* rationale

## CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted.

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(and rejected *Abbott* as inapposite) to prevent interference with action taken by the Secretary of Agriculture to halt the interstate shipment of an economic poison under Section 4(c) of the Federal Insecticide, Fungicide and Rodenticide Act, 61 Stat. 167, as amended, 7 U.S.C. 135b(c).

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